Public Comments of Albert Donnay, MHS

RE: comments for CASAC Augmented Sulfur Oxides Review Panel

IN RESPONSE TO: Federal Register, 5/27/2014

VIA: email to <u>a-and-r-Docket@epa.gov</u>

I thank EPA for giving the public this opportunity to comment on its Draft Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide and also on the draft response of the CASAC Augmented Sulfur Oxides Primary Review Panel.

The Integrated Science Assessments [ISAs] that EPA prepares for NAAQS reviews are critically important to the outcome as they greatly limit the scope of published research that EPA staff, CASAC advisors, and ultimately the Administrator consider in making their recommendations and decisions. This is especially true in recent years when EPA's ISAs—and matching HERO database, when available--have included very little of the peer-reviewed literature published during the review window but often hundreds of older studies published outside the window.

The last ISA on SO2, for example, spanned 1996-2009 and included 896 references, but only 67% of these were published in this time frame; 33% were published earlier. And the ISA left out 73.3% of the 2240 articles published on sulfur dioxide or sulfur oxides in the same period without any explanation of the reason(s) why so many were cut.

Similarly, the last ISA on CO, also released in 2009, included 808 references, but only 62% were published during the 2000-2010 window and these represented just 5.6% of the total available.

The EPA has acknowledged in response to public comments and court filings that the compilation and initial winnowing of references is not done by EPA staff but by unidentified consulting firms. EPA staff have told me that these consulting firms usually hire graduate students on a temporary basis to first winnow the bibliography down BY TITLE ALONE, deleting all those they believe do not meet EPA's [unpublished] inclusion and exclusion criteria. EPA has never kept any records of this process for any NAAQS review and claims it does not even have the bibliographies that were initially compiled.

The next round of review—which I understand is sometimes done by EPA staff—considers the abstracts of the remaining articles, and it is only from what is left after this second round of cuts that EPA staff review the full text of the remaining papers.

EPA's Tom Long told me that the final decisions about what papers to cite in any particular chapter of an ISA are left to the editors of each chapter and their contributing authors, who are usually a mix of EPA consultants and staff. They are told they can cite any studies they consider relevant, without regard to any specific inclusion or exclusion criteria, as long as they were published in peer-reviewed journals. But the chapter editors are not given a complete bibliography to consider, just the much shorter list winnowed down by the contractors.

For all these reasons, I urge the SO2 CASAC to recommend that EPA select studies for this ISA on SO2 more transparently by:

- posting the SO2 bibliography from the last NAAQS review in EPA's HERO database at http://hero.epa.gov/ [SO2 is the only one missing under the NAAQS tab];
- 2. posting the complete SO2 bibliography that EPA and/or its contractors compiles for this review from 2010 to present before it is winnowed [PubMed already lists 1032 articles in this window];
- 3. instructing staff or contractors who winnow this bibliography to never base this decision on the title alone but to always read at least the abstract and the entire paper if there is any doubt as to the relevance of the results;
- 4. publishing the inclusion and exclusion criteria in the ISA and as an introductory note in each NAAQS bibliography on HERO;
- 5. publishing summary statistics in the ISA showing the number of potentially relevant articles identified by EPA's various search strategies as described in the IRP compared to the final number cited in the ISA;
- 6. adding a one-letter field to the HERO database for all NAAQS references to indicate whether the reviewer who made the final decision to include or exclude a particular article from an ISA was an EPA consultant [C] or staff [S].

I also request that the SO2 CASAC instruct EPA not to cite any Research Reports of the Health Effects Institute [HEI] as these are not peer-reviewed journal publications in the traditional sense as EPA regulations require. They are only reviewed by paid consultants to HEI whose identities are known in advance to all the authors of the reports and vice versa; they are not published in a journal format but as a series of consecutively-numbered monographs [some published out of numerical sequence] that do not have an editor-in-chief or editorial board, publish only studies funded by HEI, never publish correspondence, and have no mechanism for considering requests for retraction. [HEI recently dismissed such a request for retraction of its Multicenter CO Study [Research Report #25] without consulting the authors and without reviewing the evidence of fabrication, falsification and plagiarism that was submitted with it.]

HEI's research reports are also redundant, since the study's key findings are usually published first in at least one traditional peer-reviewed journal. While HEI's Research Reports are indexed on PubMed, this is only because they are misrepresented as being from a journal by this name. NLM staff tell me this is inappropriate and say the most likely outcome of the investigation I have requested will be to block HEI from listing any more of its monographs on Medline or PubMed.

Finally, I urge the CASAC to insist that EPA provide all your members with access to the full text of all the articles cited in the draft and final ISA. This is especially important for older articles for which not even abstracts are available on PubMed.

Thank you for your consideration. ###